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10/686,252	10/16/2003	Cheung Hoi Yu	016660-177	7612

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/686,252	**Applicant(s)** YU ET AL.
	Examiner Suryaprabha Chunduru	**Art Unit** 1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-12,25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-24 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action filed on January 17, 2006 has been entered and acknowledged.

Status of the Application

2. Claims 13-24, 27-31 are pending. Claims 1-12, 25-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. This is made FINAL. Applicants' response to the office action is fully considered. All arguments have been fully considered and thoroughly reviewed, but are deemed persuasive in part for the reasons that follow. This action is made FINAL.

3. The following are the rejections made in the previous office action:

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13, 16, 18, 21, 23-24, 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23, and 33 of copending Application No.10/216,928 (Pub No. US 2004/0033496 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 13, 18, 23-24, 29 are generic to all that is recited in claim 23 of the co-pending application. That is, the claim 23 of the co-pending application fall entirely within the scope of claims 13, 18, 23-24, 29 or in other words, claims 13, 18, 23-24, 29 are anticipated by the claim 23 of the co-pending application. Specifically the method of steps (a) through (f) disclosing a method for detecting target DNA in a biological sample comprising providing a reaction cell formed with an aluminum oxide (dielectric material) surface being coated with a first protein to ensure the correct orientation of capture probe and adding to said cell a solution comprising capture probes (that facilitates immobilization of capture probes to said aluminum surface), adding to said cell means for generating a detectable signal (indicates supplying electrical potential or electric current to facilitate binding of target to said capture probes) and detecting signal of the claim 23 of the co-pending application are within the scope of the instant claims 13, 18, 23-24, 29. Further the instant claims 16, 21 are generic to all that is recited in the claim 33 of the co-pending application, in other words, the instant claims 16, and 21 are anticipated by claim 33, that is claim 33 of the co-pending application fall entirely within the scope of the instant claims 16 and 21. Thus the instant claims encompass the claims in the co-pending application and are related as genus and species, and are coextensive in scope.

The courts have stated that a genus is obvious in view of the teachings of a species. see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed.Cir. 1989). Therefore the instantly claimed method preparing cell lysate is obvious over the claims in the co-pending.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 13-24, 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Heller et al. (US Patent 5,605,662, reference taken from IDS submitted by the Applicants).

Heller et al. teach a method of claim 13, of performing field-assisted hybridization in the detection of nucleic acid targets from a sample comprising the steps of

(i) providing a reaction cell (micro-location on a chip) having an attachment surface formed of a dielectric material (silicon dioxide surface, a dielectric material) (see col. 12, line 47-54);

(ii) providing a metal electrode (aluminum) in direct contact with said dielectric material (see col. 12, line 55-67, col. 13, line 1-25, indicates metal layer is directly deposited in contact with the dielectric material);

(iii) attaching nucleic acid capture probes (specific binding entities) (see col. 13, line 29-67, col. 14, line 1-21, col. 18, line 23-26, indicating oligonucleotide capture probes are attached to the surface);

(iv) adding the sample to said reaction cell and providing an electrical potential to said electrode (See col. 18, line 26-36, col. 15, line 57-67, col. 16, line 1-14).

With regard to claim 14, 22, 27, Heller et al. teach that the electrode is provided in contact with a surface of said dielectric material, opposite from said attachment surface (underlying the attachment surface) (see col. 14, line 63-67; col. 15, line 1-23);

With regard to claims 15-16, 20-21, Heller et al. teach that said potential is continuous or a pulsed potential applied to said electrode (col. 17, line 45-63, col. 19, line 3-20, indicates continuous application of potential as in electrophoretic transport and applying pulsed potential as in biasing);

With regard to claim 17, Heller et al. teach that said sample comprises biological substances (DNA) (see col. 18, line 26-45);

With regard to claim 18, Heller et al. teach a method of attracting or repelling electrically-charged entities to or from a surface of a reaction cell when performing a biological reaction (hybridization) comprising the steps of providing a dielectric material as said surface and generating an electric field by inducing charge-separation in said dielectric material (see col. 18, line 23-36, col. 19, line 21-44);

With regard to claim 19, Heller et al. teach that said charge separation in said dielectric material is induced by placing electrode in direct contact with said dielectric material and applying a potential to said electrode (see col. 18, line 23-36, col. 12, lines 55-67, col. 13, lines 1-25);

With regard to claims 23-24, Heller et al. teach a method if accelerating a detection process (rapid detection process) for biological molecules performed in a reaction cell, comprising the steps of providing a dielectric material as a surface of said reaction cell, and generating an electrical field by inducing charge separation in said dielectric material (see col. 18, line 21-67, indicating rapid detection process);

With regard to claim 28-29, Heller et al. teach that said dielectric material is an oxide, selected from SiO_2 (see col. 12, 51-54);

With regard to claims 30, Heller et al. teach that said metal is formed of aluminum (see col. 12, line 55-56). Accordingly the instant claims are anticipated by Heller et al.

B. Claims 13, 15-16, 18, 20-21, 23-24, 29 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 10/216, 928 (Pub No. US 2004/0033496 A1). which has a common inventor(s) with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application.

The co-pending application discloses a method of claims 13, 18, 23-24, 29 for electrically-assisted nucleic acid hybridization comprising providing a reaction cell formed wit aluminum oxide surface (dielectric material) and attaching capture probes to said surface, adding a biological sample and adding to said cell means for generating a detectable signal in the cell and detecting said signal (see claim 23, page 7, 20-25, page 8, line 1-20, page 9, line 1-2, line 23-25). With regard to the instant claims 15-16 and 20-21, the co-pending application discloses that the hybridization steps are electronically assisted by pulse or continuously applied current (see page 9, line 23-25, page 10, line 1-5, claim 33).

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. Heller et al. (US Patent 5,605,662) in view of Gerdes et al. (USPN. 6, 291, 166).

Heller et al. teach a method of claim 31, of performing field-assisted hybridization in the detection of nucleic acid targets from a sample comprising the steps of

(i) providing a reaction cell (micro-location on a chip) having an attachment surface formed of a dielectric material (silicon dioxide surface, a dielectric material) (see col. 12, line 47-54);

(ii) providing a metal electrode (aluminum) in direct contact with said dielectric material (see col. 12, line 55-67, col. 13, line 1-25, indicates metal layer is directly deposited in contact with the dielectric material);

(iii) attaching nucleic acid capture probes (specific binding entities) (see col. 13, line 29-67, col. 14, line 1-21, col. 18, line 23-26, indicating oligonucleotide capture probes are attached to the surface);

(iv) adding the sample to said reaction cell and providing an electrical potential to said electrode (See col. 18, line 26-36, col. 15, line 57-67, col. 16, line 1-14).

Heller et al. teach that said dielectric material is an oxide, and said metal is formed of aluminum (see col. 12, 51-54, col. 12, line 55-56).

However Heller et al. did not specifically teach that said dielectric material comprising an aluminum oxide (Al_2O_3).

Gerdes et al. teach a method for irreversibly binding nucleic acid to a solid surface (electropositive solid phase materials) that can be used in DNA hybridization assays, wherein said solid surface comprises aluminum oxide (Al_2O_3) (see col. 4, line 1-5, col 13, line 19-63). Gerdes et al. also teach that aluminum oxide shows sufficient avidity for nucleic acid to bind it even at low concentrations and at high flow rates (see col. 13, line 19-47, col. 8, line 10-32).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of performing field-assisted hybridization as taught by Heller et al. in a manner as taught by Gerdes et al. by incorporating aluminum oxide (Al_2O_3) as a dielectric material for the purpose of enhancing irreversible binding of nucleic acids to said dielectric material. One skilled in the art would have been motivated to combine the method of performing field-assisted hybridization as taught by Heller et al. with a step of including aluminum oxide (Al_2O_3) as taught by Gerdes et al. because the ordinary artisan would have a reasonable expectation of success that inclusion of said dielectric parameter would result in stable and irreversible binding of nucleic acids and aid in hybridization assays as taught by Gerdes et al. (see col. 13, line 19-63) and such modification is considered as obvious over cited prior art in the absence of secondary considerations.

Response to arguments:

7. Applicants' arguments and amendment with respect to the informalities are fully considered and acknowledged the corrections made in veiw of the informalities.

8. Applicant's arguments and the amendment, filed on January 17, 2006, with respect to the objection to abstract of the disclosure have been fully considered and are persuasive. The objection has been withdrawn in view of the amendment.

9. Applicant's arguments filed on January 17, 2006 with respect to the rejection of claims 13, 16, 18, 21, 23-34, and 29 under obviousness-type double patenting have been fully considered. Applicants' request to hold the double-patenting issue in abeyance until allowable subject matter is determined, is considered however, the rejection is maintained herein until the issue is resolved.

10. Applicant's arguments filed on January 17, 2006 with respect to the rejection of claims 13-24, 27-30 under 35 USC 102(b) as being anticipated by Heller et al. have been fully considered but they are not persuasive. Applicants' argue that Heller et al. does not teach or suggest a metal layer in direct contact with the attachment layer as recited in claim 13. Rather Heller et al. teach two additional layers between the electrode and the attachment layers, and points out to the Fig. 2 of Heller et al. to support the arguments. Applicants further argue that since claims 14-17, 27-30 are dependent on claim 13, Heller et al. does not anticipate these claims. Applicants' arguments are fully considered and found unpersuasive. Applicants point out one embodiment of the Heller et al. disclosure, however, Heller et al. does teach a metal layer in direct contact with the attachment layer (chip or silicon chip) (see col. 12, line 47-67, indicating that the steps involved in making the chip in direct contact with a metal layer (aluminum circuitry pattern on chip)), this is also supported in col. 13, line 5-15). Even if the permeation layer is considered, Heller et al. teach that the permeation layer is a porous layer that prevents larger binding entities from physical contact with the microelectrode. In addition in the same col. 13, line 60-67, and col. 14, line 1-12) indicates that the derivatization of the metal microelectrode surface with APS that facilitates binding entities to covalently bound to the derivatized micro-electrode surface. Further Fig. 9a to 9C teach the hybridization process in microlocations. Thus Heller et al. does

teach or suggest metal layer in direct contact with the attachment layer. Therefore Heller et al. does anticipate the instant claims.

Applicants also argue that claim 18 recites a dielectric material as a surface of a reaction cell and Heller et al. does not teach or suggest dielectric material and claims 19-22 depend on claim 18 are also not anticipated by Heller et al. Applicants' arguments are fully considered and found unpersuasive. The instant specification discloses dielectric material as an oxide, selected from the group consisting of Al_2O_3, SiO_2, and Ta_2O_5 on page 3, line 19-20). It is noted that Heller et al. does teach dielectric material (SiO_2) is coated on silicon chip (see col. 12, line 49-54). Therefore the instant claims are anticipated by Heller et al.

Applicants, further argue that the instant claims 23-24 depend on claim 18, recite generating electrical field by inducing charge separation, and Heller et al. does not teach use of dielectric material as a surface of the reaction cell and does not anticipate the instant claims. Applicants' arguments are fully considered and found unpersuasive. As discussed above Heller et al. does teach dielectric material and also teach charge-separation in an electric field (see col. 18, line 22-36, indicates the generation of potential differences to concentrate hybridized DNA and electrode potential repels unhybridized DNA). Thus Heller et al. does anticipate the instant claims and therefore the rejection is maintained herein.

11. Applicant's arguments filed on January 17, 2006 with respect to the provisionally rejected claims 13, 16, 18, 21, 23-34, and 29 under 35 USC 102(e) have been fully considered. Applicants' request to hold the rejection in abeyance until allowable subject matter is determined, is considered however, the rejection is maintained herein until the issue is resolved.

12. Applicant's arguments filed on January 17, 2006, with regard to the rejection of claim 31 rejected under 35 USC 103(a) have been fully considered but they are not persuasive. Applicants argue that Heller et al. does note teach or suggest a metal electrode in direct contact with the attachment layer and fails to teach a dielectric material. Gerdes fails to satisfy the deficiencies of Heller. Applicants further argue Gerdes , taken alone or in combination with Heller fails to teach or suggest a reaction cell providing a metal electrode in direct contact with the dielectric material. Applicants' arguments are fully considered and found unpersuasive. As discussed above, Heller et al. does teach a metal electrode in direct contact with the attachment layer (silicon chip coated with dielectric material in contact with a metal electrode). In response to applicant's arguments that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). In this case, specific motivation is provided in the rejection above, wherein Gerdes explicitly taught the use of dielectric material in stable and irreversible binding of nucleic acids and aid in hybridization assays (see col. 13, line 19-63). One skilled in the art would have been motivated to combine the method of performing field-assisted hybridization as taught by Heller et al. with a step of including aluminum oxide (Al_2O_3) as taught by Gerdes et al. because the ordinary artisan would have a reasonable expectation of success that inclusion of said dielectric parameter would result in stable and irreversible binding of nucleic acids and aid in hybridization assays as taught by

Gerdes et al. (see col. 13, line 19-63) and such modification is considered as obvious over cited prior art in the absence of secondary considerations. Thus Heller et al. in view of Gerdes does make the instant claim 31 obvious and the rejection is maintained herein.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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3\20\06